



Inspection Report

GRIFOLS BIOLOGICALS, INC.

Customer ID: **25422**

Certificate: **93-R-0489**

Site: 001

GRIFOLS BIOLOGICALS, INC.

2410 LILLYVALE AVENUE

Type: ROUTINE INSPECTION

LOS ANGELES, CA 90032

Date: Jul-02-2009

No non compliant items identified this inspection.

Prepared By:

ALEXANDRA ANDRICOS, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5038

Jul-07-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jul-07-2009



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Date: Sep-09-2008

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

***The following is the number of animals to be used per year as described in the written and approved protocols T-1167-056 for guinea pigs, and A-6500-305 and P-1455-048 for rabbits and the actual number of animals that were on study:

From 01 Oct 05 through 30 Sep 06

	Guinea pigs	Rabbits
Number of animals approved to be used	552	1424
Actual number of animals on study	768	1642

01 Oct 06 through 30 Sep 07

	Guinea Pigs	Rabbits
Number of animals approved to be used	808	1452
Actual number of animals on study	828	1683

The facility used an additional 216 guinea pigs and 218 rabbits during 2006 and an additional 8 guinea pigs and 231 rabbits during 2007 than was approved for by the IACUC on the above mentioned protocols. There were significant changes regarding the number of animals used without prior IACUC approval. Without written approval, we cannot be certain the IACUC was aware of the number of animals that were being used. The IACUC, as an agent of the research facility, should review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.***

To be corrected by November 1, 2008

Prepared By:

ALEXANDRA ANDRICOS, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5038

Sep-19-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-29-2008



Inspection Report

3.25 (d)

FACILITIES, GENERAL.

(d) Waste disposal. Provisions shall be made for the removal and disposal of animal and food wastes, bedding, dead animals, and debris. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, and disease hazards.

*** Upon entering a guinea pig room, a moderate to strong odor of animal waste was noted. There were 2-4 empty guinea pig enclosures with a small accumulation of animal waste in one corner of each of the enclosures. The accumulation of animal waste, even for a short period of time, may lead to vermin infestation, odors and disease hazards. Enclosures should be cleaned after each animal is removed from a study to minimize the build up of odors.***

To be corrected by September 12, 2008

Prepared By:

ALEXANDRA ANDRICOS, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5038

Sep-19-2008

Received By:

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Date: Aug-07-2007

2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

During routine inspection an unlabeled syringe containing an unknown substance was found in a locked drawer in the rabbit treatment room. The presence of unlabeled medical drugs and materials can lead to their misuse and may result in unpredictable outcomes. All medical materials should be identified and labeled to ensure their proper use.
Corrected during inspection.

Prepared By:

ALEXANDRA ANDRICOS, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5038

Aug-07-2007

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Aug-08-2007